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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/177, 711 10/23/98 ADAMS

M QNS96-02A2

HM12/0711

EXAMINER

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ART UNIT	PAPER NUMBER
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1617

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DATE MAILED:

07/11/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/177,711	ADAMS ET AL.
	Examiner	Art Unit
	Shengjun Wang	1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 01 May 2001.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 60-80 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 60-80 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- 15) Notice of References Cited (PTO-892)
- 16) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 18) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 19) Notice of Informal Patent Application (PTO-152)
- 20) Other: \_\_\_\_\_

**DETAILED ACTION**

1. The request filed on May 1, 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/177711 is acceptable and a CPA has been established. An action on the CPA follows.

*Claim Objection*

2. Claim 63-65 and 73-76 is objected to as not further limiting claims 62 or 72 since the function of an ingredient employed in a method are considered inherent in the method as claimed.

*Claim Rejections 35 U.S.C. 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 60, 61, 63-71 and 73-80 are rejected under 35 U.S.C. 102(e) as being anticipated by Kock et al. (U.S. Patent 5,849,803)

Kock et al. teaches method for treatment of erectile dysfunction in men by administering to the patient nitroglycerine along with prostaglandin. See, particularly, column 2, line 32 bridging column 3, line 17 and claims 1, 6 and 11-12.

The primary reference does not teach expressly the method would be less painful compared with method wherein prostaglandin is employed alone. However, such properties is considered inherently possessed by the prior art. Applicants' attention is directed to *Ex parte*

*Novitski*, 26 USPQ2d 1389 (BOPA 1993) illustrating anticipation resulting from inherent use, absent a *haec verba* recitation for such utility. In the instant application, as in *Ex parte Novitski*, supra, the claims are directed to preventing pain associated with use of prostaglandin with old and well known compounds or compositions. It is now well settled law that administering compounds inherently possessing a protective utility anticipates claims directed to such protective use. Arguments that such protective use is not set forth *haec verba* are not probative. Prior use for the same utility clearly anticipates such utility, absent limitations distancing the proffered claims from the inherent anticipated use. Attempts to distance claims from anticipated utilities with specification limitations will not be successful. At page 1391, *Ex parte Novitski*, supra, the Board said "We are mindful that, during the patent examination, pending claims must be interpreted as broadly as their terms reasonably allow. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989). As often stated by the CCPA, "we will not read into claims in pending applications limitations from the specification." *In re Winkhaus*, 52 F.2d 637, 188 USPQ 219 (CCPA 1975)." In the instant application, Applicants' failure to distance the proffered claims from the anticipated therapeutical utility, renders such claims anticipated by the prior inherent use. Although the instant claims recite decrease pain associated with the use of prostaglandin, the steps of the method is identical to the cited prior art, i.e. administering nitroglycerine with prostaglandin to patient with sexual dysfunction.

***Claim Rejections 35 U.S.C – 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 60-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kock et al. (US Patent 5,849,803) in view of Akkus et al. (Medline Abstract, AN 95174112) and Cesar et al. (WO 94/04120)

Kock et al. teach method for treatment of erectile dysfunction in men by administering to the patient nitroglycerine along with prostaglandin. See, particularly, column 2, line 32 bridging column 3, line 17 and claims 1, 6 and 11-12.

The primary references does not teach expressly the method would be less painful compared with method wherein prostaglandin is employed alone or employing the method for female.

However, Akkus teach that prostaglandin is known to be similarly useful for female in promoting erection in genital tissue. See the abstract. Cesar et al. teach that method for treating sexual dysfunction employing prostaglandin is known to be useful both for male and female. See, page 12, line 19 bridging page 13, line 24. Further, it is well-settled patent law that mode of action elucidation does not impart patentable moment to otherwise old and obvious subject matter. Applicant's attention is directed to In re Swinehart, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered functional property, inherently possessed by thing in the prior art, does not cause a claim drawn to those things to distinguish over the prior art." Additionally, where the patent Office has reason to believe that a functionally limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to requires the applicant to prove that the subject matter shown to be in

the prior art does not possess the characteristic relied on. In the instant invention, the claims are directed to the ultimate utility set forth in the prior art.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to employ the method for female because prostaglandin is known to be similarly useful for female sexual dysfunction. Optimization of the method of administration of the active agent is considered within the skill of artisan, absent evidence to the contrary.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

S. Wang  
Shengjun Wang

AU 1617

q  
July 27, 2000

RUSSELL TRAVERS  
PRIMARY EXAMINER  
GROUP 1200